science.sciencemag.org/content/368/6495/1066/suppl/DC1

Supplementary Materials for

Filling gaps in science exposes gaps in chemical regulation

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This PDF file includes:

This pdf file includes: Supplementary text where indicated and, for further reading, additional references in support of ***bold underlined statements*** within the *main text quoted in italics* below. All web pages listed were visited in May, 2020.

BIRTH OF A NEW CHEMICAL

*"They appear to have found a use, however, **in the manufacture of fluorinated polymers** with nonstick properties..."*

References:

M. Rusconi *et al.*, Evaluating the impact of a fluoropolymer plant on a river microbenthic community by a combined chemical, ecological and genetic approach. *Science of the Total Environment* **538**, 654-663 (2015), available at http://dx.doi.org/10.1016/j.scitotenv.2015.08.086, last visited May 22, 2020.

*"As such, they helped answer an **urgent desire** to eliminate the use and release of perfluoroactonoic acid (PFOA) and its precursors and homologs,..."*

References:

Z. Wang *et al.*, Fluorinated alternatives to long-chain perfluoroalkyl carboxylic acids (PFCAs), perfluoroalkane sulfonic acids (PFSAs) and their potential precursors. *Environment International* **60**, 242–248 (2013), available at http://dx.doi.org/10.1016/j.envint.2013.08.021, last visited May 22, 2020.

US EPA, Fact Sheet: 2010/2015 PFOA Stewardship Program (Aug. 9, 2018), available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/fact-sheet-20102015-pfoa-stewardship-program, last visited May 22, 2020.

*"... which had been **widely dispersed in the environment** as a result of the production of other substances with similar properties."*

References:

N. Rich, Rob Bilott v. DuPont. *New York Times Magazine* 36 (Jan. 10, 2016), available at https://www.nytimes.com/2016/01/10/magazine/the-lawyer-who-became-duponts-worst-nightmare.html , last visited May 22, 2020.

Environmental Working Group, Poisoned Legacy: PFC Contamination : No Place to Hide (May 1, 2015), available at https://www.ewg.org/research/poisoned-legacy/pfc-contamination-no-place-hide, last visited May 22, 2020.

Z. Wang *et al.*, Global emission inventories for C_4–C_{14} perfluoroalkyl carboxylic acid (PFCA) homologues from 1951 to 2030, Part I: production and emissions from quantifiable sources. *Environment International* **70**, 62-75 (2014), available at https://doi.org/10.1016/j.envint.2014.04.013, last visited May 22, 2020.

Z. Wang *et al.*, Global emission inventories for C_4–C_{14} perfluoroalkyl carboxylic acid (PFCA) homologues from 1951 to 2030, part II: The remaining pieces of the puzzle. *Environment International* **69**, 166-176 (2014), available at https://doi.org/10.1016/j.envint.2014.04.006, last visited May 22, 2020.

D. Han *et al.*, Occurrence and source apportionment of perfluoroalkyl acids (PFAAs) in the atmosphere in China. *Atmospheric Chemistry & Physics* **19**, 14107-14117 (2019), available at https://doi.org/10.5194/acp-19-14107-2019, last visited May 22, 2020.

S. Lerner, New Jersey is making companies pay for toxic contamination – shining a new light on a little-known offender. *The Intercept* (Mar. 27, 2019), available at https://theintercept.com/2019/03/27/new-jersey-pfas-contamination/, last visited May 22, 2020.

Cooperative Research Centre for Contamination Assessment and Remediation of the Environment, Development of guidance for contaminants of emerging concern, Technical Report No. 34 (July 2014) at pp. 5, 10, available at https://www.crccare.com/files/dmfile/CRCCARETechnicalReport32-DevelopmentofGuidanceforContaminantsofEmergingConcern.pdf, last visited May 22, 2020.

*"Amid **growing evidence** that PFOA and similar compounds were highly persistent, bio-accumulative, and potentially toxic, ... :*

References:

Environmental Working Group, Poisoned Legacy: PFC Contamination : The C8 Science Panel (May 1, 2015), available at https://www.ewg.org/research/poisoned-legacy/c8-science-panel, last visited May 22, 2020.

C. Lau, *Perfluorinated Compounds: An Overview*, in Toxicological Effects of Perfluoroalkyl and Polyfluoroalkyl Substances 1-21 (J.C. DeWitt, ed.) (Humana 2015).

R. Renner, *PFOA in People*, Environmental Science & Technology **41**, 4497 (2007), available at https://pubs.acs.org/doi/10.1021/es0725697, last visited May 22, 2020.

*"... as well as a spate **of private lawsuits** and..."*

References:

Ala. Residents Sue 3M for Toxic Pollution, Andrews Environmental Litigation Reporter **25(7)**, 2 (Nov. 5, 2004).

Court OKs DuPont Teflon Deal, $357 Million Payout Possible, Andrews Environmental Litigation Reporter **23(24)**, 14 (Jan. 6, 2006).

DuPont Facing $5 Million Suit Over Teflon Pollution, Andrews Toxic Torts Litigation Reporter **24(7)**, 5 (May 12, 2006).

*"... increasing **state and federal government** scrutiny,..."*

References:

EPA, *Press Release: EPA Settles PFOA Case Against DuPont for Largest Environmental Administrative Penalty in Agency History* (Dec. 14, 2005), available at https://www.epa.gov/enforcement/reference-news-release-epa-settles-pfoa-case-against-dupont-largest-environmental, last visited May 22, 2020.

EPA, *Press Release: EPA Settles Case Involving 3M Voluntary Disclosures of Toxic Substances Violations* (Apr. 25, 2006), available at https://archive.epa.gov/epapages/newsroom_archive/newsreleases/440f8e8e3e28707e8525715b007186f7.html, last visited May 22, 2020.

EPA, *Press Release: EPA Reaches Agreement with DuPont to Protect Drinking Water Near W.Va. Plant* (Nov. 21, 2006), available at https://archive.epa.gov/epapages/newsroom_archive/newsreleases/d71a299a96058ad58525722d00542655.html, last visited May 22, 2020.

DuPont to Pay $10.25 Million Fine for Withholding Teflon Data , Andrews Toxic Torts Litigation Reporter **23(25)**, 10 (Jan. 20, 2006).

Ass'n of State Drinking Water Administrators, "Per- and Polyfluoroalkyl Substances (PFAS) State Drinking Water Program Challenges," available at https://www.asdwa.org/pfas/,last visited May 22, 2020.

New Jersey Dept. of Environmental Protection, Statewide PFAS Directive, Information Request and Notice to Insurers (Mar. 25, 2019), available at https://www.nj.gov/dep/docs/statewide-pfas-directive-20190325.pdf, last visited May 22, 2020.

New York State Dept. of Environmental Conservation, Guidelines for Sampling and Analysis of PFAS (Jan. 2020), available at https://www.dec.ny.gov/docs/remediation_hudson_pdf/pfassampanaly.pdf, last visited May 22, 2020.

*"... **eight companies voluntarily agreed** ..."*

Supplementary text:

The eight agreeing companies were Arkema, Asahi, BASF Corporation (successor to Ciba), Clariant, Daikin, 3M/Dyneon, DuPont, and Solvay Solexis.

References:

EPA, "Fact Sheet: 2010/2015 PFOA Stewardship Program," available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/fact-sheet-20102015-pfoa-stewardship-program, last visited May 22, 2020.

*"**to work toward eliminating** **PFOA** from emissions and in product content" in the United States by 2015*

Supplementary text:

The companies also committed "to reducing PFOA and related chemicals from facility emissions and in product content by 95% no later than 2010."

References:

EPA, 2010/15 PFOA Stewardship Program: Guidance on Reporting Emissions and Product Content at 3 (Oct. 2006), available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2006-0621-0016 (search for "guidance"), last visited May 22, 2020.

*"By the time of this agreement between the companies and the U.S. Environmental Protection Agency (EPA), the phase-out of PFOA was **already well underway informally**."*

Supplementary text:

Some of the agreeing companies told EPA that they had already met the Stewardship Program's goal for 2010 by the time the Program began in 2006. For example, Solvay Solexis, Inc. reported in 2006 that "Solexis has already achieved a greater than 95% reduction from the 2000 baseline year, of PFOA product residual and facility emissions to all environmental media."

References:

Letter from Michael Lacy (President, Solvay Solexis) to Stephen L. Johnson (Administrator, EPA), March 1, 2006 at 1, available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2006-0621-0005, last visited May 22, 2020.

PUBLIC TOXICITY INFORMATION

*"In the United States, regulators in California have expressed serious concerns that **perfluoroether carboxylic acids—a class that includes the ClPFPECAs**, 'may have similar or higher toxic potency than the longer-chain PFAAs [perfluoroalkyl acids] they are replacing'...."*

Supplementary text:

A draft version of the report cited in the main text includes an Appendix consisting of a table listing numerous PFASs by category. In that table, which was not appended to the final report, ClPFPECAs are included among the perfluoroether carboxylic acids.

References:

California Department of Toxic Substances Control, Product-Chemical Profile for Carpets and Rugs Containing Perfluoroalkyl or Polyfluoroalkyl Substances, Discussion Draft at p. 115 (Feb. 2018), available at https://dtsc.ca.gov/wp-content/uploads/sites/31/2018/10/Product-Chemical-Profile-PFAS-Carpets-and-Rugs.pdf, last visited May 22, 2020.

*"Toxicity testing has revealed **reason for concern** about some of these alternatives...."*

References:

S. Lerner, New Jersey Is Making Companies Pay for Toxic Contamination – Shining a New Light on a Little-Known Offender. *The Intercept* (Mar. 27, 2019), https://theintercept.com/2019/03/27/new-jersey-pfas-contamination/, last visited May 22, 2020.

S. Lerner, EPA allowed companies to make 40 new PFAS chemicals despite serious risks. *The Intercept* (Sept. 19, 2019), https://theintercept.com/2019/09/19/epa-new-pfas-chemicals/, last visited May 22, 2020.

Danish Ministry of the Environment, Environmental Protection Agency. Survey of PFOS, PFOA and other perfluoroalkyl and polyfluoroalkyl substances (Version for Public Consultation), at p. 108 (Nov. 27, 2012), available at https://www2.mst.dk/Udgiv/publications/2013/04/978-87-93026-03-2.pdf, last visited May 22, 2020.

Z. Wang et al., Hazard assessment of fluorinated alternatives to long-chain perfluoroalkyl acids (PFAAs) and their precursors: Status quo, ongoing challenges and possible solutions, Environment International **75**, 172 (2015), available at http://dx.doi.org/10.1016/j.envint.2014.11.013, last visited May 22, 2020.

*"GenX and other PFAS chemicals have also been **detected in environmental media at levels that raise regulatory concern**."*

References:

Z. Wang et al., Hazard assessment of fluorinated alternatives to long-chain perfluoroalkyl acids (PFAAs) and their precursors: Status quo, ongoing challenges and possible solutions, Environment International **75**, 172 (2015), available at http://dx.doi.org/10.1016/j.envint.2014.11.013, last visited May 22, 2020.

Y. Wang et al., A review of sources, multimedia distribution and health risks of novel fluorinated alternatives, Ecotoxicology & Environmental Safety **182**, 109402 (2019), available at https://doi.org/10.1016/j.ecoenv.2019.109402, last visited May 22, 2020.

New Jersey Dept. of Environmental Protection, Statewide PFAS Directive, Information Request and Notice to Insurers (Mar. 25, 2019), available at https://www.nj.gov/dep/docs/statewide-pfas-directive-20190325.pdf, last visited May 22, 2020.

*"In response to our request for further information under the E.U.'s Public Access to Documents Regulation, **EFSA provided titles and dates for the three unpublished studies** listed in the dossier, but the names and affiliations of the authors were withheld as personal data."*

Supplementary Text:

The European Union's Public Access to Documents Regulation grants EU citizens a right of access to certain documents and allows EU institutions to grant similar access to non-EU citizens.

EFSA provided the following timely response to our initial request for information:

We are pleased to provide you with all references to scientific research on toxicity testing underlying the dossier concerned and referred to in the relevant EFSA scientific opinion:

- **Subject matter - Genotoxicity, Gene mutation in bacteria**: 2006. Fluorolink 7850 Bacterial Mutation Assay (*S. typhimurium* and *E.coli*). Final Report, Research Toxicology Centre Study no.: 52400, 1-58;
- **Subject matter - Genotoxicity, In vitro mammalian cell gene mutation test**: 2006. Fluorolink 7850 Mutation in L5178Y TK+/- Mouse Lymphoma Cells (Fluctuation Method). Final Report, Research Toxicology Centre Study no.: 52410, 1-72;
- **Subject matter - Genotoxicity, In vitro mammalian chromosome aberration test**: 2006. Fluorolink 7850 Chromosome aberrations in Chinese Hamster ovary cells in vitro. Final Report, Research Toxicology Centre Study no.: 52420, 1-49.

Please note that all of the above references concern unpublished study reports. Since names of authors of unpublished studies constitute personal data, they are not disclosed to you in application of the exception to disclosure in Article 4(1)(b) of the PAD Regulation. In accordance with settled case law of the Court of Justice of the European Union (CJEU), this exception to disclosure is to be interpreted as a reference to Regulation (EU) 2018/1725 (hereinafter "the Data Protection Regulation"). Article 9(1)(b) of the Data Protection Regulation deals with personal data transmissions to recipients established in the Union. Taking account of the case law referred to above, EFSA will only be able to balance the interests at stake and to consider the disclosure of personal data after you have provided an express and legitimate justification and convincing arguments in order to demonstrate the necessity of having personal data transmitted to you for a specific purpose in the public interest in the sense of Article 9(1)(b) (so-called *'necessity test'*).

References:

Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001, Art. 2, ¶¶ 1, 2, available at https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32001R1049&from=EN, last visited May 22, 2020.

Email message from EFSA to Steve Gold dated Apr. 30, 2020.

*"As we went to press on 29 May, we were **still awaiting a response from EFSA** to our further request for access to the full dossier, because the studies cannot be found in the public domain."*

Supplementary Text:

We have created a separate web-link that will be updated with information from EFSA in response to our request: https://utexas.box.com/s/xl3n7a3p61djiu2xysadjtupev3ummcz . Our last contact, on May 12, indicated that "EFSA is still in the process of clarifying the confidential status of the requested documents" and they would be back in touch with us on June 5 in accordance with Article 7(3) of the PAD Regulation.

References:

Email message from EFSA to Steve Gold dated May 12, 2020, uploaded to https://utexas.box.com/s/xl3n7a3p61djiu2xysadjtupev3ummcz.

"We found an entry for the ClPFPECAs that includes an "executive summary" of the available data in 32 categories of information relevant to toxicity or hazard; ***no data or values*** *are shown for any of the 32 categories."*

Supplementary text:

We found the entry for ClPFPECAs by searching for the product's CAS Number, 329238-24-6. Each Comptox entry includes a number of "tabs" that summarize and link to available data about the categories listed in the Executive Summary. For ClPFPECAs, all of the data tabs were empty as of May 22, 2020.

References:

EPA, "Perfluoro-1-propene telomer with chlorotrifluoroethene, oxidized, reduced, hydrolyzed: 329238-24-6 | DTXSID10883083: Searched by CAS-RN," available at https://comptox.epa.gov/dashboard/dsstoxdb/results?search=329238-24-6#exec_sum, last visited May 22, 2020.

THE REGULATORY STORY

"This type of comparative analysis seems particularly appropriate in light of the voluntary phase-out of PFOA, all the more so since EPA has identified approximately 500 ***PFAS*** *chemicals sold in US commerce, out of a* ***larger, global list of thousands of such compounds****."*

References:

EPA, "EPA's Per- and Polyfluoroalkyl Substances Action Plan," Feb. 19, at p. 11-12, available at https://www.epa.gov/sites/production/files/2019-02/documents/pfas_action_plan_021319_508compliant_1.pdf, last visited May 18, 2020.

EPA, "PFAS Master List of PFAS Substances," available at https://comptox.epa.gov/dashboard/chemical_lists/pfasmaster, last visited May 18, 2020.

"The resulting, ***publicly available research on PFAS chemicals is quite limited****."*

Supplementary text:

The Danish Ministry of the Environment, reporting to the EU, stated: "Information related to human health is available for only a few of the several hundreds of polyfluorinated chemicals (PFCs) used in industry and consumer products."

References:

Danish Ministry of the Environment, Environmental Protection Agency. Survey of PFOS, PFOA and other perfluoroalkyl and polyfluoroalkyl substances (Version for Public Consultation), at p. 113 (Nov. 27, 2012), available at https://www2.mst.dk/Udgiv/publications/2013/04/978-87-93026-03-2.pdf, last visited May 22, 2020.

*"However, assessments for PFAS chemicals appear to have been conducted – at best – on an ad hoc basis and **primarily through negotiated agreements**.*

References:

EPA, "EPA's Per- and Polyfluoroalkyl Substances Action Plan," Feb. 19, at p. 26, available at https://www.epa.gov/sites/production/files/2019-02/documents/pfas_action_plan_021319_508compliant_1.pdf, last visited May 18, 2020.

*"EPA has now instituted more uniform **comparative assessment procedures for some PFAS chemicals**, but these apply only to new polyfluroalkyl chemicals or uses **produced after 2015**."*

References:

EPA, "Risk Management for Per- and Polyfluoroalkyl Substances (PFAS) under TSCA," Feb. 20, available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-and-polyfluoroalkyl-substances-pfas, last visited May 18, 2020.

*"A search through EPA's TSCA inventory, however, provides more unsolved mysteries: the ClPFPECA family is not listed (by CAS number) in EPA's public inventory of over **40,000 registered chemicals**."*

References:

EPA, "How to access the TSCA inventory," Mar. 20, available at https://www.epa.gov/tsca-inventory/how-access-tsca-inventory, last visited May 18, 2020.

*"One is that although the law generally requires pre-manufacture notification of "new" chemicals (developed after 1976) to submit a pre-manufacture notification, there are **multiple exemptions from this registration requirement**."*

References:

EPA, "Filing a Pre-manufacture Notice with EPA," Apr. 20, available at https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/filing-pre-manufacture-notice-epa#exempt, last visited May 18, 2020.

*"It is unclear whether the ClPFPECAs satisfied any of these exemptions, which allow manufacturers to avoid submitting a pre-manufacture notification, for example, on new chemicals that are **long-chain polymers** or that are only impurities."*

References:

EPA, "Questions and Answers for the New Chemicals Program," Sep. 15, at p. 2-1, 3-12, available at https://www.epa.gov/sites/production/files/2015-09/documents/qanda-newchems_new.pdf, last visited May 19, 2020.

*"Currently, more than **140 unidentified PFAS chemicals** in U.S. commerce are **classified as CBI**, according to EPA."*

References:

EPA, "PFAS Laws and Regulations," Jul. 18, available at https://www.epa.gov/pfas/pfas-laws-and-regulations, last visited May 18, 2020.

*"The agency is still working on this assignment, with about **two thousand chemicals left to review**."*

References:

EPA, "Statistics for the TSCA CBI Review Program," Apr. 20, available at https://www.epa.gov/tsca-cbi/statistics-tsca-cbi-review-program, last visited May 18, 2020.

*". . . and EPA's own statistics show that **only 10%** of the new chemicals entering commerce between 1979 and 2016 involved restrictions or testing orders."*

References:

EPA, "Statistics for the New Chemicals Review Program under TSCA," May 20, available at https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review, last accessed May 18, 2020 (Click tab "Statistics prior to June 22, 2016).

*This catch-22 resulted in a **paucity of testing orders**.*

References:

EPA, "Sunset dates of chemicals subject to final TSCA section 4: test requirements and related 12(b) actions," Dec. 18, available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/sunset-dates-chemicals-subject-final-tsca-section-4-test, last visited May 20, 2020.

*. . . the burden of chemical-assessment rests almost entirely **on a small group of EPA regulators**."*

References:

United States Government Accountability Office, "Status of EPA's Efforts to Produce Assessments and Implement the Toxic Substances Control Act," Mar. 2019, at p. 34, available at https://www.gao.gov/assets/700/697212.pdf, last visited May 20, 2020.

Wendy Wagner, *Using Competition-Based Regulation to Bridge the Toxics Data Gap*, 83 INDIANA L. J. 629, 632 (2008).

WENDY WAGNER, INCOMPREHENSIBLE! A STUDY OF HOW OUR LEGAL SYSTEM ENCOURAGES INCOMPREHENSIBILITY, WHY IT MATTERS, AND WHAT WE CAN DO ABOUT IT at 130-57 (Cambridge University Press 2019)

*"Manufacturers **can also sue the agency in court**, arguing that some aspect of the agency's analysis might be arbitrary."*

References:

WENDY WAGNER, INCOMPREHENSIBLE! A STUDY OF HOW OUR LEGAL SYSTEM ENCOURAGES INCOMPREHENSIBILITY, WHY IT MATTERS, AND WHAT WE CAN DO ABOUT IT 143-146 (Cambridge University Press 2019)

*"And **ClPFPECAs are listed** – along with five hazard classifications – in the EU's notification (CLP) database."*

References:

ECHA, Information on Chemicals, Search for Chemicals (using CAS Number 329238-24-6) https://echa.europa.eu/information-on-chemicals. CIPFPECAs Chemical Infocard available at https://echa.europa.eu/substance-information/-/substanceinfo/100.207.408, last visited May 21, 2020.

*"Additionally, in 2005, the European Union **implemented REACH**...."*

References:

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006, available at https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02006R1907-20200227&from=EN, last visited May 22, 2020.

P. Fisk, Chemical Risk Assessment: A Manual for REACH (John Wiley & Sons 2014).

*"Yet a search by CAS number **returns no results for ClPFPECAs** on the European Chemical Agency's web site that lists registered REACH chemicals."*

References:

ECHA, "Registered Substances," May 20, available at https://echa.europa.eu/information-on-chemicals/registered-substances, last visited May 18, 2020.

*"Perhaps ClPFPECAs are produced in low enough quantities (**less than 1 tonne/year**) to be exempted from REACH . . ."*

References:

ECHA, "Do I reach the one tonne a year threshold?," available at https://echa.europa.eu/support/registration/your-registration-obligations/do-i-reach-the-one-tonne-a-year-threshold, last visited May 18, 2020.

". . . or perhaps ClPFPECAs satisfy other REACH exemptions, such as those ***governing impurities or polymers*** *as defined under REACH."*

References:

ECHA, "Guidance for identification and naming of substances under REACH and CLP," May 17, at p. 24-29, available at https://echa.europa.eu/documents/10162/23036412/substance_id_en.pdf/ee696bad-49f6-4fec-b8b7-2c3706113c7d, last visited May 18, 2020.